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10/536,586	03/17/2006	Masakazu Takeuchi	082368-004500US	9187

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TOWNSEND AND TOWNSEND AND CREW, LLP
TWO EMBARCADERO CENTER
EIGHTH FLOOR
SAN FRANCISCO, CA 94111-3834

EXAMINER	
CHERNYSHEV, OLGA N	
ART UNIT	**PAPER NUMBER**
1649	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/536,586	TAKEUCHI ET AL.	
	Examiner	Art Unit	
	Olga N. Chernyshev	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 January 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,7,8 and 10-13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4,5, 7 and 10-13* is/are rejected.

7)☒ Claim(s) *2,3 and 8* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. Claims 1-5 and 7 have been amended and claims 10-13 have been added as requested in the amendment filed on January 30, 2008. Following the amendment, claims 1-5, 7, 8 and 10-13 are pending in the instant application.

Claims -5, 7, 8 and 10-13 are under examination in the instant office action.

2. Any objection or rejection of record, which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

3. Applicant's arguments filed on January 30, 2008 have been fully considered but they are not deemed to be persuasive for the reasons set forth below.

Claim Objections

4. Claims 2, 3 and 8, as currently amended, are objected to under 37 CFR 1.75(c) as being in improper form because any dependent claim, which refers to more than one other claim ("multiple dependent claim ") shall refer to such other claims in the alternative only, emphasis added. See MPEP § 608.01(n). In the instant case claims 2 and 3 are multiple dependent claims because they depend from claim 1 or claim 10, which also depends from claim 1, thus making both claims depend from the same claim 1. Accordingly, the claims 2, 3 and 8 have not been further treated on the merits.

5. New claim 10 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Claim 10 depends from claim 1, which is limited to a nucleic acid encoding a protein, while claim 10

encompasses a compliment of SEQ ID NO: 2, thus making the claims mutually exclusive. Therefore, claim 10 can be infringed by a nucleic acid, which does not infringe claim 1. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Applicant should note the "Infringement Test" for dependent claims in MPEP § 608.01(n). The test for a proper dependent claim is whether the dependent claim includes every limitation of the parent claim. A proper dependent claim shall not conceivably be infringed by anything, which would not also infringe the basic claim. In the instant case, the compliment nucleic acid claim could be infringed without infringing the claim from which it depends, i.e. the encoding nucleic acid claim. Therefore, it is improperly dependent and should be rewritten in independent form.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1, 4, 5 and 7, as currently amended and new claims 10-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

8. Claims 1, 5 and 7 are vague and ambiguous for recitation "an amino acid sequence that binds PSD-95". Applicant is advised that a sequence is not a material limitation but a characteristic of a molecule and, therefore, by itself cannot bind anything. Amending the claims to recite "a polypeptide that binds PSD-05" would better express the claimed subject matter, perhaps.

9. Claims 1, 5, 7, 12 and 13 are further indefinite for reciting "PSD-95", "PET" and "LIM" as limitations. Applicant is advised that without spelling out the acronyms, or supporting the terms with a proper SEQ ID NO, the skilled artisan cannot appraise the scope of the claimed subject matter.

10. Claim 4, 10 and 11 are indefinite for being dependent from indefinite claim.

Claim Rejections - 35 USC § 101

11. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

12. Claims 1, 4, 5 and 7, as currently amended, and new claims 10-13 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial credible asserted utility or a well-established utility for those reasons of record as applied to claims 1-5 and 7-8 in section 7 of Paper mailed on August 30, 2007.

Applicant traverses the rejection on the premises that, "[t]he m-Prickle protein possesses three LIM domains and one PET domain, as shown in Figure 4, and discussed in Example 4 of the specification. At the time of filing the application, a skilled artisan would recognize that each of the LIM domains can function as a protein interaction module (see, e.g., abstract of Dawid I.B., et al. (1998) Trends in Genet. 14:156-162; and abstract of Bach, I. (2000)Mech. Dev. 91:5-17, copies of which are enclosed as Exhibits 1 and 2, respectively). Similarly, the skilled artisan would also understand that the PET domain is likely involved in interactions with other proteins, such as actin cytoskeletal components (see, e.g., page 2325, left col. lines 1-7 of Gubb, D., et al. (1999) Genes Dev. 13:2315-2327, a copy of which is enclosed as Exhibit 3). The presence of the

highly conserved LIM and PET domains in the m-Prickle protein, would lead the skilled artisan to reasonably understand that the m-Prickle protein acts either as a scaffold protein, or as an integral part of a scaffold complex" (p. 10 of the Response). Applicant further argues that because "the m-Prickle protein is concentrated in a post-synaptic density (PSD) fraction [it] is reasonably expected to interact with numerous other proteins through the highly conserved LIM and PET domains, the skilled artisan would also reasonably expect that the m-Prickle protein is involved in the structural organization of the PSD", and that "the skilled artisan would reasonably expect the m-Prickle proteins and nucleic acids of the invention to be a potential target for affecting the physiological processes underlying learning and memory" (bottom at the same page). Applicant's arguments have been fully considered but are not persuasive for the following reasons.

As fully explained in the previous office action of record, to be patentable, an invention must be useful in currently available form. The instant claimed polynucleotides encoding a novel naturally occurring mammalian polypeptide (and fragments thereof), of which is known that it is highly homologous to the "protein involved in *Drosophila* plannar cell polarity, and is known to regulate the direction of wing hair in *Drosophila*", and further that the protein "may participate in the formation of synaptic polarity and/or JNK signaling through its interaction with Dsh in mammals as well" (p. 1 of the instant specification), lack practical utility in currently available form because the instant specification fails to disclose its real world biological significance, relevance to a specific clinical condition or any other meaningful information that would allow their immediate and beneficial use. The Examiner maintains that the relationship between structure of the instant rat protein of SEQ ID NO: 1 and its ability to bind other proteins (the

presence of LIM and PET domains) does not provide a utility for the claimed nucleic acids and fragments of the encoded proteins. Furthermore, there appears to be no evidence of record to support Applicant's argument that proteins found in the post-synaptic fraction are expected "to be a potential target for affecting the physiological processes underlying learning and memory" (p. 11 of the Response).

Furthermore, the evidence of record is inadequate to support Applicant's statement that, "[b]ecause m-Prickle is known to bind PSD-95, which is known to associate with NMDA-Rs in the PSD, and m-prickle can be co-precipitated with NMDA-Rs, the skilled artisan would understand that manipulation of m-Prickle can be used to modulate the processes underlying learning and memory at the cellular level" (p. 12 of the Response). The Examiner maintains that in the absence of knowledge of the biological significance of this specific nucleic acid of SEQ ID NO: 2 and the encoded protein of SEQ ID NO: 1, there is no immediately obvious patentable use for the polynucleotide or the encoded protein. The instant specification states that "mPrickle is expected to be applicable for the diagnosis of learning- and memory-related disorders such as mental deterioration and dementia in the future" (p. 3), but provides no further evidence that the instant nucleic acid or encoded protein are associated with any disease or disorder. The specification provides no meaningful guidance regarding how to use the limited information characterizing polypeptide of SEQ ID NO: 1 in any specific and substantial way.

Applicant claims a product asserted to be useful in "in designing experimental systems for screening compounds that affect the clustering of NMDA-Rs" (p. 12 of the Response) but the specification does not disclose how to interpret this statement. Just as the process claimed in *Brenner* lacked utility because the specification did not disclose how to use the end-product, the

product claims here lack utility, based on their use, e.g. "to modulate the processes underlying learning and memory at the cellular level" (p 11 of the Response), because the specification does not disclose how to use the SEQ ID NO: 1 or 2 in any meaningful way to achieve the stated purpose.

The Court in *Brenner v. Manson* held that "[t]he basic *pro quid quo* contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility. Unless and until a process is refined and developed to this point – where specific benefit exists in currently available form – there is insufficient justification for permitting an applicant to engross what may prove to be a broad field." Id. at 534-35, 148 USPQ at 695.

For reasons of record fully explained earlier and reasons above, the instant rejection is maintained.

Claim Rejections - 35 USC § 112

13. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

14. Claims 1, 4, 5, 7 and 10-13 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial credible asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

17. Claims 5 and 7, as amended, are further rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 5 and 7 are directed to fragments of polynucleotides and polypeptides defined as comprising at least eight amino acids "and a PET domain" (for metes and bounds of "PET domain" limitation, see rejection of record in section 9 of the instant office action). The claims do not require that the fragments possess any particular conserved structure or other disclosed distinguishing feature specifically associated with and being responsible for the "mammalian" protein and the ability of the fragment to bind PSD-95. Thus, the claims are drawn to a genus of polynucleotides and a genus of polypeptides that are defined only by limited (and vague and indefinite, see section 9) strutural similarity. However, the instant specification fails to describe the entire genus of nucleic acids and proteins, which are encompassed by these claims.

As fully explained in section 11 of the previous office action of record, the instant specification only describes a protein having the amino acid sequence of SEQ ID NO: 1 and a polynucleotide of SEQ ID NO: 2 and fails to teach or describe any other molecule which lacks these sequences and has any relevance to R-Prickle gene. There is no identification of any particular portion of the structure that must be conserved and it is not even clear what region of the encoded polypeptide has the activity, which is associated with biological significance of R-prickle (see also reasons of record in section 12 of the instant office action explaining that the function of the polypeptide of SEQ ID NO: 1 is currently not known). Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification

does not provide adequate written description of the claimed genus and the instant rejection is maintained.

Claim Rejections - 35 USC § 102

18. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

19. Claims 5 and 7, as currently amended, stand rejected under 35 U.S.C. 102(b) as being anticipated by Drmanac et al., 2001, for reasons of record in section 18 of Paper mailed on August 30, 2007.

Applicant traverses the rejection on the premises that, "[c]laims 5 and 7 as presently amended recite that the polypeptide fragment comprises at least eight amino acid residues and a PET domain. Drmanac et al. does not teach nor suggest a polypeptide fragment having at least eight amino acid residues and a PET domain as presently claimed" (p. 15 of the Response). Applicant's argument has been fully considered but is not persuasive for the reasons that follow.

Claims 5 and 7 encompass fragments comprising at least eight amino acid residues of polypeptide of SEQ ID NO: 1 and polynucleotides encoding these fragments, respectively. The claims have been amended to recite that the fragments comprise "a PET domain". However, the metes and bounds of the recitation cannot be determined from the claims or the instant specification as filed (see section 9 of the instant office action). Specifically, claim 13 appears to be defining PET domain as "corresponding to position 19-89 […] of SEQ ID NO: 1", which

makes the domain at least 69 amino acids long. Because the instant specification fails to provide the meaningful definition of the PET domain, claims 5 and 7 by broadest reasonable interpretation encompass fragments comprising eight amino acids of the polypeptide comprising SEQ ID NO: 1 and the polypeptides of Drmanac et al. fully meet the limitations of the claims. Applicant is further advised that due to the use of the open end "comprising" language, the claims also read on any fragment of eight amino acids in existence.

Conclusion

20. No clam is allowed.

21. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (571) 272-0870. The examiner can normally be reached on 8:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey J. Stucker can be reached on (571) 272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

April 8, 2008

/Olga N. Chernyshev, Ph.D./
Primary Examiner, Art Unit 1649